GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

UNSTARRED QUESTION NO:636
ANSWERED ON:24.11.2006
TRANSFER OF BIO MATERIALS
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Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) Whether Indian Sub-group on Clinical Research and Transfer of Biomaterials under Indo-US Joint Industry working group on Biotechnology recommended for a new drug authority body on the lines of TRAI and IRDA ;

(b) If so, the details thereof;

(c) The other recommendations made for bringing about regulatory and fiscal changes to remove procdural and other impediments in biotechnology sector ;

(d) Whether the biotechnology industry is also demanding to treat clinical research expenditure as R&D expenditure; and

(e) If so, the reasons therefor and the benefits to the industry therefrom ?

Answer

MINISTER OF SCIENCE & TECHNOLOGY AND MINISTER OF EARTH SCIENCES (KAPIL SIBAL)

(a) & (b) Yes, Sir. The proposal suggests that the New Drug Authority be an independent statutory body on the lines of TRAI, IRDA etc., headed by an officer of appropriate level and guided by a Scientific Advisory Board.

(c) Other recommendations are

A. Regulatory

1) A single window clearance mechanism with standard operating procedures(SOPs) forimport and export of biologicals; clinical trial and pharmacogenomic samples and export of Special Chemicals, Organisms, Materials, Equipment & Technoogies(SCOMET) items.

2) Development of policy guidelines for clinical trials.

B. Fiscal

1) Income Tax : Clinical Research Expenditure be treated as R & D Expenditure.

2) Customs:

i) Allowing import of laboratory consumables by recognized R&D units up to Rs 1.00 crore .

ii) Removal of anomaly in duty structure between public and private sector.

iii) Permitting unrestricted import for R&D by National Accreditation Board Ltd .

(NABL) accredited laboratories.

3) Central Excise : Exemption of central excise duty for goods that are exempted from customs duty.

4) Service Tax : Exemption of service tax for Clinical Trial industry.

(d) & (e) Yes, Sir. The reasons advanced for such demand is that clinical research requires substantial R&D inputs and is a critical component of new product development and that such reliefs would make them more competitive and encourage innovation.